United States Senate
COMMITTEE ON HEALTH, EDUCATION
LABOR, AND PENSIONS
WASHINGTON, DC 20510-6300

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October 31, 2005

Dr. Andrew von Eschenbach
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

We are writing to commend the Food and Drug Administration for its prompt release of draft guidance on the reuse of single-use medical devices, and to clarify Congressional intent with respect to the effective date of the reuse provision of the Medical Device User Fee Stabilization Act (MDUFSA; P.L. 109-43).

As you know, section 2(c) of MDUFSA amended section 502(u) of the Federal Food, Drug, and Cosmetic Act, which addresses the circumstances under which the reprocessor of a single-use medical device must mark the device with its own name or symbol. That section requires FDA to issue guidance, no later than 180 days after August 1, 2005, regarding when a manufacturer name or symbol on a device is not "prominent and conspicuous."

We commend FDA for promptly issuing draft guidance on this issue (70 FR 59074, October 11, 2005; Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended–Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices) and hope that the agency will be able to finalize the guidance by the statutory deadline.

We would like to clarify an important issue in the guidance, however, which we expect will be corrected in the final guidance. Section 2(d) of MDUFSA provided for an effective date for the changes of section 2(c) by amending section 301 of the Medical Device User Fee and Modernization Act of 2002 (P.L. 107-250). Section V.2 of the guidance misinterprets this effective date provision. It indicates that, if the original manufacturer first marks a device prominently and conspicuously before August 1, 2006, the reprocessor must mark it by August 1, 2006, and if the manufacturer first marks the device after August 1, 2006, the reprocessor must immediately mark the device. This does not reflect the intent of section 2(d) of MDUFSA.

We intended this provision to allow the reprocessor to mark the device 12 months after August 1, 2005, or 12 months after the device is first marked by the

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original manufacturer, whichever date is later. This intent is reflected in the following language from the MDUFSA report (S Rept 109-107):

> *Subsection (d) amends section 301(b) of MDUFMA to make the amendment made by subsection (c)(1) to section 502(u) of the FFDCA effective 12 months after the date of enactment of the act, or 12 months after the original manufacturer has first marked its device, if that is later*

It would clearly be impossible for a reprocessor to mark a device immediately upon the marking of such device by the original manufacturer. The intent was to give reprocessors a uniform 12 months to complete the marking (though we anticipate the marking could and would occur more quickly).

We respectfully ask that you revise the guidance to reflect our intent regarding the date by which a reprocessed single-use device must be marked. If you have any questions, please fee free to contact Amy Muhlberg with Senator Enzi at 202-224-2465 or David Dorsey with Senator Kennedy at 202-224-6064. Thank you.

Sincerely,

Michael B Enzi
Chairman

Ted Kennedy

Edward M. Kennedy
Ranking Member